

Appl. No. 09/558,465

Atty. Docket No. 7546M

Amdt. dated March 7, 2005

Reply to Office Action of December 7, 2005

Customer No: 27752

REMARKS

Claims 1 – 9 and 11-34 are pending in the present application. No additional claims fee is believed to be due.

The Rejection under 35 U.S.C. 103(a) over Ramachandran et al in view of Cardin et al.

Claims 1-9 and 11-34 have been rejected under 35 U.S.C. as being unpatentable over Ramachandran et al (WO96/29983) in view of Cardin et al (US 5,104,645). The Examiner has asserted that it would have been obvious to include the anti-dandruff of Cardin in the teachings of Ramachandran because Cardin teaches anti-dandruff shampoos comprising 1-hydroxy-2-pyridinethione salt in platelet particle form having a specified particle size and similarly Ramachandran teaches shampoo compositions comprising therapeutics agents (i.e. ketoconazole, ZPT, etc) in shampoos. The expected result would be an effective antidandruff composition that exhibits increased efficacy. Applicants respectfully traverse this rejection.

The previous submitted Declaration by of David S Dunlop under 37 C.F.R. 1.132, dated August 11, 2003, was asserted not to be persuasive by the Examiner. The Examiner has asserted that although the art does not explicitly teach the instant bioavailability/coverage index and second conditioning index amounts, these amounts were not viewed as critical, since Applicants have not demonstrated that the prior art would not achieve effective conditioning results using the ingredients taught in the art.

Applicants now submit a further Declaration of David S. Dunlop under 37 C.F.R. 1.132., dated March 7, 2005 in order to demonstrate that the prior art would not achieve each and every index result using the ingredients taught in the art.

In order for a composition to meet the present invention's required limitations, the following 4 indices must be met: i) has a bioavailability/coverage index value, of at least about 1.25; ii) has a first conditioning index value, of less than or equal to about 1.0; iii) has a second conditioning index value, of at least about 1.5; and iv) has a minimal inhibitory concentration index value, of at least about 0.125.

In the present Declaration of David S. Dunlop under 37 C.F.R. 1.132, Formula A is representative of the present invention and representative of the Examples found in the specification on pages 56-57 comprising Viscasil 300,000, Cetyl Alcohol, Guar

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Hydroxypropyltrimonium chloride having a molecular weight of about 200,000 from Aqualon, Hydrogenated Polydecene, zinc pyrithione, and surfactants.

Formula B is representative of a formula as disclosed and claimed in Ramachandran et al (WO 96/29983) wherein the formula comprises an anionic surfactant, an amphoteric surfactant and a therapeutic agent, namely climbazole.

Formula C is representative of a formula as disclosed and claimed in Cardin et al (US 5,104,645) wherein the formulas comprised a synthetic surfactant, a 1-hydroxy-2-pyridinethione metal salt in platelet form, a synergizer, a suspending agent and water.

In Table 1, Formula A, representative of the present invention, meets all of the required criteria for the present invention for the bioavailability/coverage index, the first conditioning agent, the second conditioning index and the minimal inhibitory concentration index. Formula B, representative of a formula as disclosed and claimed in Ramachandran et al, does not meet the criteria for the minimal inhibitory concentration index. Formula C, representative of a formula as disclosed and claimed in Cardin et al., does not meet the criteria for the bioavailability/coverage index and does not meet the criteria for the second conditioning index. Thus, only Formula A, representative of the present invention, meets all of the criteria as specified by the present invention. The Applicants have demonstrated that the prior art, namely Ramachandran et al. and Cardin et al., do not achieve all of the required 4 indices of the present invention. Therefore, Applicants have demonstrated that the prior art would not achieve each effective indices using the ingredients taught in the art.

The Examiner has asserted that Ramachandran et al. do not teach that the zinc salt of 1-hydroxy-2-pyridinethione is in platelet form. Further, the Examiner has asserted that Cardin et al. has been relied upon because it teaches that when the platelet form of a pyridinethione metal salt with a specified particle size is combined with any of a group of synergizers in a shampoo matrix, that an unexpected substantial improvement in antidandruff efficacy is realized. And therefore, it would have been obvious to one of skill in the art to include the anti-dandruff of Cardin et al. within the teachings of Ramachandran et al., with the expected result to be an effective antidandruff composition that exhibits increased efficacy.

However, Applicant's would like to direct the Examiner's attention to the attached Declaration. Formula C, representative of a formula as disclosed and claimed in Cardin et al., does not meet the criteria for the bioavailability/coverage index and does not meet the criteria for the second conditioning index. Specifically, Cardin et al. does not meet the criteria for the bioavailability/coverage index, which is indicative of anti-dandruff efficacy provided by the shampoo. (see specification at pages 41-44.) Generally, the higher the index value of the composition, the better its anti-dandruff efficacy, due to

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increased bioavailability of the anti-dandruff agent, increased coverage of the anti-dandruff agent, or both. The Declaration demonstrates that Formula C failed to meet the criteria for the bioavailability/coverage index, as required by the present invention.

Therefore, Applicants have demonstrated that the prior art, namely Cardin et al., would not achieve effective or improved anti-dandruff efficacy results using the ingredients taught in the art. Further, the Examiner's assertion that it would have been obvious to one of skill in the art to include the anti-dandruff of Cardin et al. within the teachings of Ramachandran et al., *with the expected result to be an effective anti-dandruff composition that exhibits increased efficacy* (emphasis added), has been traversed, as demonstrated by the data in the Declaration.

Further, the Examiner has asserted that Ramachandran et al. claims in claim 10 the that the composition further contains a hair conditioning agent "selected from the group consisting of organosilicon compounds, aminosilicones, water insoluble hydrocarbons,...a and mixtures thereof, present at a level of from about 0.2% to 5% by weight." And the Examiner asserts that Ramachandran et al. teaches at page 10, lines 4-32, specific hair conditioning agents, including guar hydroxylpropyl trimethylammonium chloride. The Examiner further asserts that with regard to the molecular weight of the guar derivatives and the charge densities of the cellulose derivatives, one of ordinary skill in the art would be capable of determining suitable molecular weights and charge densities through routine experimentation, based on the intended purpose, to obtain the most optimal results. The Examiner states that the teachings of the art are not limited to the examples disclosed therein, since the art does recognize and teach various cationic polymers and also teach conditioning agents. Merely that the art teach the above-named ingredients in shampoo compositions is sufficient.

However, the attached 1.132 Declaration demonstrates that Applicants have surprising found through much investigation and invention, the specific criteria required to meet the specified and distinct index values, as defined and claimed, in order to achieve the surprising benefits of the present invention. In particular, Table 2 demonstrates that Formula D, representative of the present invention and comprising a cationic polymer having a low molecular weight guar meets the required criteria for the present invention for a second conditioning index, wherein Formula E, comprising a higher molecular weight/charge guar (C17 Guar), does not meet the required criteria for a second conditioning index. The Applicants made this discovery through undue experimentation and analysis of many components which are interacting within the composition. This discovery was not achieved through routine experimentation.

Further, Ramachandran et al. does not disclose the combination of a cationic polymer with a non-volatile conditioning agent. The conditioning agents are listed as one of many

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possible ingredients in the final shampoo composition. Within the category of conditioning agents, cationic polymer is mentioned in a long list of potential ingredients, none of which is required. The possible shampoo formulations that can be devised by selecting items from Ramachandran et al. optional ingredients number in the hundreds. A shampoo combining an anionic surfactant, a non-volatile conditioning agent, an anti-dandruff particulate, a cationic polymer derivative and water is only one of these hundreds of possible shampoo formulations. The data in the Declaration has demonstrated that the one conditioning agent cannot be added in place of another conditioning agent, and deliver the same result. And the discovery was made through undue experimentation and surprising results. Applicants have surprising found through much investigation and invention, the specific criteria required to meet the specified and distinct index values, as defined and claimed, in order to achieve the surprising benefits of the present invention, as demonstrated by 1.132 Declaration.

In summary, the 1.132 Declaration demonstrates representative Formula B as disclosed and claimed in Ramachandran et al, does not meet the criteria for the minimal inhibitory concentration index. Likewise, Formula C, representative of a formula as disclosed and claimed in Cardin et al., does not meet the criteria for the bioavailability/coverage index and does not meet the criteria for the second conditioning index. Further, Applicants have surprising found through much investigation and invention, the specific criteria required to meet the specified and distinct index values, as defined and claimed, in order to achieve the surprising benefits of the present invention, as demonstrated by 1.132 Declaration.

Applicants have demonstrated that the prior art, namely Cardin et al., would not achieve effective or improved anti-dandruff efficacy results using the ingredients taught in the art. Further, the Examiner's assertion that it would have been obvious to one of skill in the art to include the anti-dandruff of Cardin et al. within the teachings of Ramachandran et al., *with the expected result to be an effective anti-dandruff composition that exhibits increased efficacy* (emphasis added), has been traversed, as demonstrated by the data in the Declaration.

Therefore, Applicants' contend that the claimed invention is unobvious and that the rejection should be withdrawn.

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Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103(a). Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-9 and 11-34.

Respectfully submitted,

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